



JUL 25 2002

President  
2 1st Century Laboratories, Inc.  
21 19 South Wilson Street  
Tempe, Arizona 85282-2034

Dear Sir/Madam:

This is in response to your submissions to the Food and Drug Administration (FDA), dated June 6, 2002. Your submissions appear to be intended to be the notification required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. **Your** submissions do not meet this requirement in that the notices do not contain the signature of a responsible individual nor do they certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a).

Nonetheless, in resubmitting your notifications, you should be aware that some products bear claims that do not appear to be claims subject to 21 U.S.C. 343(r)(6).

The product **Arthri-Flex** uses the claim "...and repair the damage that causes the pain." This claim is a disease claim because it suggests that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that "joint pain" is characteristic of **arthritis** and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR

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101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there “normal pain levels,” a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

The product **Organic Flaxseed Oil** uses the claim “...omega3 fatty acids may..help maintain normal cholesterol levels.” The product **Balanced Cholesterol** uses the claim “Promotes desirable cholesterol levels...have a positive effect promoting desirable cholesterol levels.” The product **Omega 3** uses the claim “...helps control cholesterol.” In the preamble to the January 6, 2000 final rule on structure/function claims for dietary supplements (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. FDA considers a cholesterol claim not qualified as described above to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10,7520 Standish Place, Rockville, Maryland 20855.

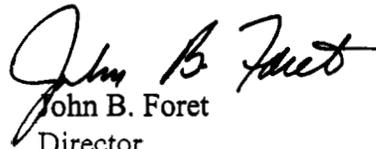
Your submission also states that the product **Liquid Filled Calcium + D** uses the claim “Reduced calcium levels may increase the **risk** for developing osteoporosis.” This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationships between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim for calcium on the label or in the labeling of a food or dietary supplement that is not in

Page 3 - President, 21<sup>st</sup> Century Laboratories, Inc.

accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, namely, osteoporosis.

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "John B. Foret". The signature is written in a cursive style with a large initial "J".

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Readily absorbable liquid calcium plus vitamin D for strong & healthy bones. (and) Reduced calcium levels may increase the **risk** for developing osteoporosis.

Dietary ingredient(s) to which the statement refers: Vitamin D, Calcium Carbonate.

Name of the supplement **bearing** the label or associated with the labeling: 21st Century Laboratories, Inc.,

Liquid Filled Calcium + D 90ct, UPC #7-40985-22653-7

Respectfbly submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear *Sirs*,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Supports healthy heart and helps control cholesterol.

Dietary ingredient(s) to which the statement refers: Fish Body Oil (source of EPA & DHA).

Name of the supplement bearing the label **or** associated with the labeling: 21st Century Laboratories, Inc.,

Omega 3 60ct, UPC #7-40985-21495-4

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Promotes desirable cholesterol levels. (and) shown in peer reviewed clinical studies to **have a** positive effect promoting desirable cholesterol levels without harmful side effects.

Dietary ingredient(s) to which the statement refers: Cycladol (Peruvian Cucumber)

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Balanced Cholesterol 90ct, UPC #7-40985-22397-0

Respecthllly submitted,

2 1st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the ~~type~~ of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Contains Omega 3-6-9 Fatty Acids to support healthy estrogen levels and for healthy triglycerides & cholesterol levels. (and) GMO free Organic Flaxseed ~~oil~~ contains high ~~lignan~~ content to support healthy estrogen levels and Omega-3-6-9 Fatty Acids for healthy triglyceride levels. (and) Research show these omega-3 fatty acids may support a healthy heart and help maintain ~~normal~~ cholesterol levels.

Dietary ingredient(s) to which the statement refers: Flaxseed ~~oil~~

Name of the supplement ~~bearing~~ the label or associated with the labeling: 21st Century Laboratories, Inc.,

Organic Flaxseed Oil 1000mg 60ct, UPC #7-40985-22407-6

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

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Office of Special Nutritionals (HFS-450)  
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200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Helps rebuild cartilage and supports healthy joint function. (and) Arthri-Flex will nourish cartilage and lubricate joints to improve flexibility, comfort and range of motion and repair the damage that causes the pain.

Dietary ingredient(s) to which the statement refers: Ester C™ Calcium Ascorbate, **Magnesium** Glycinate, Zinc Glycinate, Copper Glycinate, Manganese Glycinate, Molybdenum Glycinate, Glucosamine Sulfate, MSM, Chicken Sternal Collagen type 11, Boron Glycinate, Boswellin, Grape Seed extract, White Willow **Bark** extract.

Name **of** the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Arthri-Flex 180ct, UPC #7-40985-22642-1  
Arthri-Flex 120ct, UPC #7-40985-22623-0

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of **Special** Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 **S.** Wilson Street, Tempe, AZ 85282.

Statement(s): The Natural Choice To Promote Cartilage Regeneration And Support Healthy Joints. (and) These compounds found in the **soft** cartilage, tendons and synovial fluid are essential to the healthy functioning of tendons and joints, especially with advancing age.

Dietary ingredient(s) to which the statement refers: Glucosamine Sulfate and Chondroitin Sulfate.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Maximum Strength Glucosamine and Chondroitin 180ct, UPC #7-40985-22639-1

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of **21** USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): The important trio of minerals + vitamin D to help build strong bones and teeth. (and) This important trio +D also helps to maintain normal heart and muscle functions.

Dietary ingredient(s) to which the statement refers: Vitamin D, Calcium Carbonate, Magnesium Oxide, Zinc Oxide.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Cal Mag Zinc + D 90ct, UPC #7-40985-22263-8

Respecthllly submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

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6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Essential mineral for weight control. (and) Studies suggest a correlation between chromium consumption and a significant reduction in body fat and increased muscle **mass**.

Dietary ingredient(s) to which the statement refers: Chromium Picolinate.

Name of the supplement bearing the **label** or associated with the **labeling**: 21st Century Laboratories, Inc.,

Chromium Picolinate 200mcg 100ct, UPC #7-40985-21368-1

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Essential Nutrient for Normal Functioning Heart, Kidneys, and Nervous System. (and) Potassium helps regulate water balance within the body. (and) Studies have shown potassium works to control the activity of the heart muscle, nervous system and kidneys.

Dietary ingredient(s) to which the statement refers: Potassium Gluconate.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Potassium 99mg 110ct, UPC #7-40985-21387-2

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): The Super Antioxidant **to** Help Protect the Body From Free Radicals.

Dietary ingredient(s) to which the statement refers: Selenomax (tm) High Selenium Yeast.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Selenium 200mcg 60ct, UPC #7-40985-21154-0

Respectlly submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): 21<sup>st</sup> Century's Zinc 50mg aids in carbohydrate metabolism and assimilation of nutrients. (and) Zinc helps to maintain normal cell growth and development.

Dietary ingredient(s) to which the statement refers: *Zinc Amino Acid Chelate*.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Zinc 50mg 110ct, UPC #7-40985-21393-3

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.



2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

6/10/02

Office of Special Nutritionals (HFS-450)  
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200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's **name** and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): 21<sup>st</sup> Century's Zinc 100mg aids in carbohydrate metabolism and assimilation of nutrients. (and) Zinc helps to maintain normal cell growth and development.

Dietary **ingredient(s)** to which the statement refers: Zinc **Amino** Acid Chelate.

Name of the supplement **bearing** the label or associated with the labeling: 21st Century Laboratories, Inc.,

Zinc 100mg 11Oct, UPC #7-40985-22671-1

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of **21 USC 343(r)(6)**, we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. **21 19 S.** Wilson Street, Tempe, AZ **85282.**

Statement(s): Natural **soy** for female body, heart and bone health.

Dietary ingredient(s) to which the statement refers: Soy Isoflavones extract.

Name of the supplement bearing the label or associated with the labeling: **21st** Century Laboratories, Inc.,

Soy Support 60ct, UPC #7-40985-22330-7

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



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Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Natural **soy** for female body, heart and bone health.

Dietary ingredient(s) to which the statement refers: Soy Isoflavones extract.

Name of the supplement **bearing** the label or associated with the **labeling**: 21st Century Laboratories, Inc.,

Soy Support **60ct**, UPC #7-40985-22330-7

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Promotes tissue repair and production of antibodies, hormones and enzymes.

Dietary ingredient(s) to which the statement refers: L-Lysine

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

L-Lysine 90ct, UPC #7-40985-21062-8

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
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200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): 100% natural enhancer for healthy sexual function. (and) Horny Goat Weed Complex offers a natural alternative for enhanced performance by increasing youthful vigor without the need for harsh stimulants or caffeine. (and) effective for both men and women, restoring sexual desire, reducing fatigue, boosting erectile function in men and alleviating menopausal discomfort in women. (and) unique combination of exotic herbs from around the world, provide the required **stamina** and endurance necessary to achieve peak performance.

Dietary ingredient(s) to which the statement refers: Horny Goat Weed, Yohimbe extract, Tribulus Terristris extract, Oyster, Potency Wood, Damiana.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Horny Goat Weed Complex 120ct, UPC #7-40985-22666-7

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: **21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.**

Statement(s): Restore desire with the natural enhancer for healthy **sexual** function. (and) **Horny Goat Weed** (*Epimedium sagatatum*) in studies has shown to create **a** natural libido-lift restoring sexual desire in men and women. (and) Maca (*Lepidium meyenii*) **has** been used for centuries by native Peruvians **as** an all natural enhancer for sexual function.

Dietary ingredient(s) to which the statement refers: Horny Goat Weed extract, Maca.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Horny Goat Weed Plus Maca 60ct, UPC #7-40985-22665-0

Respectfully submitted,

**21st Century Laboratories, Inc.**

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10102

Office of Special Nutritionals (HFS-450)  
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200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's name **and** address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Helps protect the retina and macula of the eye.

Dietary ingredient(s) to which the statement refers: Lutein

Name of the supplement **bearing** the **label** or associated with the **labeling**: 21st Century Laboratories, **Inc.**,

Lutein 10mg 60ct, UPC #7-40985-22408-3

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



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Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): To support a good nights rest.

Dietary ingredient(s) to which the statement refers: Melatonin.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Melatonin 3mg 90ct, UPC #7-40985-21240-0

Respectfully submitted,

**21**st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
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Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Maximum Strength for healthy digestive function.

Dietary ingredient(s) to which the statement refers: Papaya fruit, Bromelain, Papain.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Papaya Enzyme 100ct, UPC #7-40985-22662-9

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.



21 19 South Wilson ~~Street~~, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-921-9300

6/10/02

Office of Special Nutritionals (HFS-450)  
**FDA-CFSAN**  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Restores Sexual Desire. (and) Yo'Horny offers a natural alternative for enhanced performance by increasing youthful vigor without the need for harsh stimulants or caffeine. (and) effective for both men and women, restoring **sexual** desire, reducing fatigue, boosting erectile function in men and alleviating menopausal discomfort in women. (and) proprietary blend of exotic herbs to provide the required **stamina** and endurance necessary to achieve peak performance.

Dietary ingredient(s) to which the statement refers: Zinc Oxide, Tribulus Terrestris extract, Epimedium Sagitatum extract, Yohimbe extract, Maca, Potency Wood, Avena Sativa extract, Ginkgo Biloba, 1-Arginine, Saw Palmetto.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Yo'Horny 120ct, UPC #7-40985-22654-4

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/10/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's name **and** address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Essential for use of calcium necessary for healthy bones, teeth, and cartilage.

Dietary ingredient(s) to which the statement refers: Vitamin D.

Name of the supplement bearing the label or associated with the **labeling**: 21st Century Laboratories, Inc.,

Vitamin D-400 100ct, UPC #7-40985-22661-2

Respectfbly submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): The "new age" antioxidant, a potent free radical fighter.

Dietary ingredient(s) to which the statement refers: Alpha Lipoic Acid

Name of the supplement bearing the **label** or associated with the labeling: 21st Century Laboratories, Inc.,

Alpha Lipoic Acid 50mg 90ct, UPC #7-40985-2 1674-3

Respecthllly submitted,

2 1st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 e fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Essential vitamins & minerals + Marine Protein extract for supple & smooth Skin.

Dietary ingredient(s) to which the statement refers: Vitamin C, Calcium, Zinc, Marine Protein.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Beautiful Skin 90ct, UPC #7-40985-22555-4

Respectlly submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): A natural biochemical for cellular energy production in the heart.

Dietary ingredient(s) to which the statement refers: CoEnzyme Q10

Name of the supplement **bearing** the **label** or associated with the **labeling**: 21st Century Laboratories, Inc.,

CoEnzyme Q10 30mg 30ct, UPC #7-40985-21341-4

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's **name** and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): **A** natural biochemical for cellular energy production in the heart. (and) CoEnzyme Q10 is essential for the health of all body organs.

Dietary ingredient(s) to which the statement refers: CoEnzyme Q10

Name of the supplement **bearing** the label or associated with the labeling: 21st Century Laboratories, Inc.,

CoEnzyme Q10 60mg 50ct, UPC #7-40985-21800-6

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

**Manufacturer's name** and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

**Statement(s)**: A natural biochemical for cellular energy production in the heart. (and) CoEnzyme Q10 is essential for the health of all body organs.

**Dietary ingredient(s)** to which, the statement refers: CoEnzyme Q10

**Name** of the supplement bearing the ~~URL~~ or associated with the labeling: 21st Century Laboratories, Inc.,

CoEnzyme Q10 100mg 50ct, UPC #7-40985-22337-6

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement **to** which that section refers.

Manufacturer's name and address: **21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.**

Statement(s): **A natural biochemical for cellular energy production in the heart. (and) CoEnzyme Q 10 is essential for the health of all body organs.**

Dietary **ingredient(s)** to which the statement refers: CoEnzyme Q10

Name of the supplement **bearing** the label **or** associated with the **labeling**: **21st Century Laboratories, Inc.,**

CoEnzyme Q10 200mg 30ct, UPC #7-40985-22687-2

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear *Sirs*,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): A formula of vital amino acids to help your body build & repair muscle damage.

Dietary ingredient(s) to which the statement refers: *Amino* Acids from Whey Protein Concentrate

Name of the supplement **bearing** the label or associated with the labeling: 21st Century Laboratories, Inc.,

Daily Amino Acid 120ct, UPC #7-40985-22557-8

Respectfbly submitted,

2 1st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 o fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): DHEA thought to mediate the aging process.

Dietary ingredient(s) to which the statement refers: DHEA (Dehydroepiandrosterone)

Name of the supplement bearing the **label** or associated with the **labeling**: 21st Century Laboratories, Inc.,

DHEA-25mg 90ct, UPC #7-40985-21177-9

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): An essential building block for healthy Hair, Nails, **Skin**, and Cartilage.

Dietary ingredient(s) to which the statement refers: Gelatin

Name of the supplement bearing the **label** or associated with the **labeling**: 21st Century Laboratories, Inc.,

Gelatin 600mg 100ct, UPC #7-40985-22663-6

Respecthly submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Proprietary enzyme blend maximizes healthy digestion. (and) Digestive Enzymes is a proprietary digestive enzyme blend formulated to maximize healthy digestive function.

Dietary ingredient(s) to which the statement refers: Amylase, Protease, Cellulase, Lactase, Lipase.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Digestive Enzymes 60ct, UPC #7-40985-22556-1

Respectfully submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

21 19 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 21 19 S. Wilson Street, Tempe, AZ 85282.

Statement(s): vitamins and minerals to support healthy eye function.

Dietary ingredient(s) to which the statement refers: Beta Carotene, Vitamin C, Vitamin E, Calcium, Zinc, Selenium, Copper.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Healthy Eyes 60ct, UPC #7-40985-22319-2

Respectfbly submitted,

21st Century Laboratories, Inc.

# 21<sup>ST</sup> Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



6/18/02

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear **Sirs**,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the **type** of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Natural Herbs, Vitamins, and Minerals To Nourish Hair, **Skin**, & Nails. (and) advanced formula containing natural herbs with vitamins and minerals to enhance beauty from within for today's active women

Dietary ingredient(s) to which the statement refers: Vitamin **A**, Vitamin C, Vitamin D, Vitamin E, **Thiamin**, **Riboflavin**, Niacin, Vitamin B6, Folic Acid, Vitamin B12, Biotin, Pantothenic Acid, Calcium, Iron, Phosphorus, Iodine, Magnesium, Zinc, Manganese, Potassium, Choline, Betaine, Inositol, PABA, DNA, RNA, Tyrosine, Cysteine, Glutamic Acid, Lysine, Leucine, Aspartic Acid, Isoleucine, Valine, Alanine, Arginine, Histidine, Serine, Threonine, Glycine, Ornithine, Brewers Yeast, Soy Protein, Horsetail, Parsley, Rose Hips, Watercress, Citrus Bioflavonoids, Lecithin, Rutin.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Hair, **Skin** & Nails 50ct, UPC #7-40985-21434-3

Respectfully submitted,

21st Century Laboratories, Inc.